UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
Antimicrobials Division

May 30, 2001

MEMORANDUM:

Subject: Efficacy Review EPA Reg. No. 72977-R and 72977-E Axenohl and Axen
DP Barcode 274402 and 274407
Case No. 065218 and 652118

From: Nancy Whyte, Microbiologist NW
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Thru: Emily Mitchell, M.S., Team Leader
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Thru: Michele E. Wingfield, Chief
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Applicant: ETI H_2O
Route 15, PO Box 1517
Lake City FL 32024

Formulation Label:

Active Ingredient(s)	**% by wt.**
Silver*	0.0012%
Citric acid	4.8400%
Inert Ingredients	95.1588%
Total	100.0000%

*Electronically generated silver ions

I. Background:

The registrant has submitted two data packages for review of efficacy data to support

the registration of both a manufacturing-use product and an end-use product. The MUP (*Axenhol)* is used to formulate end-product disinfectants. The end-product (*Axen)* is distributed in a spray bottle for disinfection of hard, non-porous environmental surfaces in homes and and institutions. The efficacy data was conducted on the MUP and submitted for review in one volume (MRID No. 450169-06).

II. Use Directions:

The directions for use printed on the label for *Axen* specify that surfaces to be disinfected should be sprayed with Axen and allowed to stand for one minute. There are no other directions for use on the end- product label. The MUP *Axenhol* label states that the product is to be diluted !:199 with 4.76% aqueous citric acid for manufacturing use only.

III. Agency Standards for Proposed Change:

The Agency standard for hard surface, non-porous surface disinfectants is found in DIS-TSS-1 and -2 which specifies that the Association of Official Analytical Chemists (AOAC) Use-Dilution Test or Germicidal Spray Product Test be used in testing. This procedure requires that sixty carriers must be tested against each of both *Salmonella choleraesuis,* ATCC 10708 and *Staphylococcus aureus,* ATCC 6538, with each of three batches of the product, one of which must be at least 60 days old. If the product is to be used in health care facilities, the product must also be tested against *Pseudomonas aeruginosa,* ATCC 15442 (180 carriers per sample, a total of 40 carriers) The product must demonstrate that it kills all organisms on 59 out of each 60 carriers in order to support label claims for its effectiveness against these organisms. If additional disinfectant claims are made for other organisms, ten carriers for each specific organism must be tested with each of 2 samples, representing different batches (10 carriers per sample, a total of 20 carriers for each organism). Killing of all organisms on all carriers is required to demonstrate effectiveness.

IV. Summary of Submitted Study:

Efficacy testing to support registration requirements for this product were conducted by MicroBioTest, Inc. in Sterling, Va. in October 1999. A Good Laboratory Practices Statement was included with results of the efficacy study. According to the protocol included in the data submitted to the Agency, the testing procedure followed the AOAC *Official Methods of Analysis,* 15th edition. 1990 Use-Dilution Test. Three lots of *Axenhol*, Lot #AG-006, prepared in April 1999, Lot #8991, prepared in September 1999, and Lot #8995, prepared also in September 1999 were used as the testing material. The samples received from the registrant were prepared at the testing facility by adding one gram of the active test agent to 199 grams of 5%(w/w) citric acid solution to achieve a 200-gram final dilution. This dilution is equivalent to the ready-to-use end-product *Axen.* No organic soil load was added. Polished stainless steel penicylinders were used as carriers. Strains of *Salmonella choleraesuis*, ATTC 10708, *Staphylococcus aureus*, ATCC 6538, and *Pseudomonas aeruginosa*, ATCC 15442 from stock culures were transferred daily for three consecutive days prior to use. Gram stains were used to verify growth. The inoculated cylinders were exposed to the product samples for 10 minutes at 20° +/-! C. The inoculum confirmation counts for each organism were as follows: *Sal. choleraesuis,* 1.1×10^8, *S. aureus , 4.2 x* 10^8, and *Pseudomonas aeruginosa*, 1.1×10^8. Following incubation at 37 +/- 2° C for 48 hours, 59 of 60 carriers showed no growth when exposed to the product for 10 minutes, confirming the effectiveness of the product. All sterility

and viability control cultures met the criteria for a valid test.

V. Labeling:

1. This label is need of a complete re-working.

2. The word "germs" must be removed from page two of the label.

3. The terms "tile" and "porcelain" must be preceded by the word "glazed"

4. In the section **Fast/Easy/Effective:** the specific items and locations in basements, attics, storage areas, vacation homes , and boat interiors must be listed. These areas are too general for label claims.

5. No efficacy testing has been done for any *Streptococcus ssp.* The term "Streptococcus" must be removed.

6. Since no organic soil load was added in the efficacy testing procedure, a pre-cleaning step should be included in the directions especially in sick rooms, pet areas, and diaper pails

7. The complete scientific names of the organisms tested for which label claims are made should be listed; i.e., *Salmonella choleraesuis, Pseudomonas aeruginosa, Staphylococcus aureus*

8. The exposure time listed on the label for *Axen* is I minute. Efficacy testing was conducted with an exposure time of 10 minutes. The words "one minute" must be replaced with "ten minutes". Additional directions for completely wetting the surfaces , and any directions for removing any excess product must be added.

VI. Comments and Recommendations:

1. The manufacturing-use product *Axenhol* when tested at a !:199 dilution (equivalent to the end-use product *Axen)* demonstrated effectiveness against *Salmonella choleraesuis,* ATCC 10708, *Staphyloccocus aureus*, ATCC 6538, and *Pseudomonas aeruginosa, ATCC 15442* exposed to the product for ten minutes.

2. The use of an organic soil load should be considered for future testing of other organisms that might be added to label claims.

Product Manager Please Note:

Please arrange a meeting with the registant's consultant Mr. Jacoby to conduct a full label review of these products and give him instructions on how to format an acceptable label. He is aware that the attached label is woefully inadequate.